

But E1

reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, wherein said recovered fibrinogen polymerizes when provided in solution at said site at a concentration of about 10 mg/ml thereof or less, to a fibrin network having therapeutically effective strength, and said composition further comprising a sufficient amount of one or more physiologically-compatible solutes such that said composition, if formulated as a lyophilized material, can be reconstituted therefrom at room temperature in sterile water for injection in about 30 minutes or less, at about 25 mg/ml of said fibrinogen; wherein about 95%, or greater, of total protein present in said composition is fibrinogen.

Q1
conclude

2. (Amended) A therapeutic composition effective on contact with thrombin at a site of treatment in a patient as a tissue adhesive, hemostat or sealant, said composition comprising non-autologous, non-single donor mammalian, clottable fibrinogen recovered from a process comprising precipitating fibrinogen from a sample of non-human, mammalian blood plasma with polyethylene glycol 1000 and reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, wherein said recovered fibrinogen polymerizes when provided in solution at said site at a concentration of about 30 mg/ml thereof or less, to a fibrin network having therapeutically effective strength, wherein said composition contains less than about 30% (w/w), based on total protein mass present therein, of proteins other than fibrinogen, and said composition further comprises a sufficient amount of one or more low molecular weight physiologically-compatible solutes such that said composition, if formulated as a lyophilized material, can be reconstituted therefrom at room temperature in sterile water for injection in about 30 minutes or less, at about 25 mg/ml of said fibrinogen.

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Sub E27

13. (Amended) A reactive therapeutic composition effective on contact at a site of treatment in a patient as a tissue adhesive, hemostat or sealant, said composition comprising, per milliliter thereof, between about 0.05 and about 500 NIH units of thrombin and also, per milliliter, between about 5 and about 30 mg of a fibrinogen composition wherein clottable fibrinogen is recovered from a process comprising precipitating fibrinogen from a sample of non-human, mammalian blood plasma with polyethylene glycol 1000 and reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, said recovered fibrinogen polymerizes to a fibrin network having therapeutically effective strength, when present at said site at a concentration of about 30 mg/ml or less; wherein about 95%, or greater, of total protein present in said fibrinogen composition is fibrinogen.

Please cancel claims 18-25 without prejudice.

Please cancel claims 27-34 without prejudice.

Remarks

Applicants respectfully request reconsideration of the subject application in view of the preceding amendments and for the following reasons. No new issues are raised that would require a further search. Accordingly, the Examiner is respectfully requested to enter and consider the Amendment and Remarks set forth herein, which are believed to place the application in condition for immediate allowance. A Notice of Allowance is therefore respectfully requested.

As an initial matter, the Office Action indicates that claims 1-14 and 18-34 are pending in the subject application, of which claims 18-34 have been